

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMGEN INC. and AMGEN	)	Civil Action
MANUFACTURING LIMITED,	)	
	)	No. 2:17-cv-01235-MRH
Plaintiffs,	)	
	)	Judge Mark R. Hornak
v.	)	
	)	
MYLAN INC., MYLAN	)	<b><u>Electronically Filed</u></b>
PHARMACEUTICALS INC., MYLAN	)	
GMBH and MYLAN N.V.,	)	
	)	
Defendants.	)	

**STIPULATION AND ~~PROPOSED~~ ORDER FOR ENTRY  
OF JUDGMENT OF NON-INFRINGEMENT REGARDING U.S. PATENT NO. 9,643,997**

WHEREAS Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") filed a complaint against Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, "Mylan") in the Western District of Pennsylvania on September 22, 2017 (ECF No. 1), and a first amended and supplemental complaint on February 7, 2019 (ECF No. 210), alleging, among other things, infringement of U.S. Patent Number 9,643,997 (the "'997 Patent");

WHEREAS Mylan has appeared and denied infringement, and Mylan has counterclaimed for declaratory judgment of non-infringement and invalidity of the '997 Patent (ECF Nos. 27, 220);

WHEREAS Amgen provided its Disclosure of Asserted Claims and Infringement Contentions on March 7, 2018 and its First Amended Disclosure of Asserted Claims and Infringement Contentions on September 20, 2018, asserting that Mylan infringes claims 9, 10, 13, 15-20, 21, 24-28, and 29-30 of the '997 Patent;

WHEREAS Mylan provided its Non-Infringement Contentions regarding the '997 Patent and its Invalidity Contentions regarding the '997 Patent on March 28, 2018;

WHEREAS the Court issued a Claim Construction Order and Claim Construction Opinion construing certain terms of the asserted claims on November 20, 2018 (ECF Nos. 171, 172);

WHEREAS Amgen provided its Second Amended Disclosure of Asserted Claims and Infringement Contentions on December 21, 2018 “applying the Court’s claim constructions” and asserting infringement of claims 16-18 and 25-27;

WHEREAS Mylan provided its Amended Non-Infringement Contentions regarding the ’997 Patent and its Amended Invalidity Contentions regarding the ’997 Patent on January 11, 2019;

WHEREAS the claims of the ’997 Patent recite “(d) washing the separation matrix; and (e) eluting the protein from the separation matrix”;

WHEREAS the claims of U.S. Patent No. 8,940,878 (the “’878 Patent”), which is related to the ’997 Patent, recite “(f) washing the separation matrix; and (g) eluting the protein from the separation matrix . . .”;

WHEREAS on May 8, 2019, the Federal Circuit affirmed the Northern District of California’s judgment of non-infringement of the ’878 Patent in the appeal captioned *Amgen Inc. v. Sandoz Inc.*, Nos. 2018-1551, 2018-1552;

WHEREAS on June 7, 2019, Amgen filed a petition for rehearing *en banc* in *Amgen Inc. v. Sandoz Inc.*, Nos. 2018-1551, 2018-1552;

WHEREAS on September 3, 2019, the Federal Circuit granted-in-part Amgen’s petition to the extent that the language “applies only in exceptional cases and” is removed from the panel opinion, and otherwise denied Amgen’s petition;

THEREFORE Amgen and Mylan agree that:

1. Amgen and Mylan stipulate that, under the reasoning of the Federal Circuit’s decision as to the ’878 Patent in *Amgen Inc. v. Sandoz Inc.*, Nos. 2018-1551, 2018-1552, Mylan’s

accused process does not meet the claim limitation “(d) washing the separation matrix; and (e) eluting the protein from the separation matrix” in the ’997 Patent, and thus Mylan does not infringe any of the asserted claims of the ’997 Patent within the meaning of any provision of 35 U.S.C. § 271.

2. Amgen and Mylan stipulate that the Court may enter a judgment of non-infringement in favor of Mylan and against Amgen for the Third and Fourth Counts of Amgen’s First Amended and Supplemental Complaint filed on February 7, 2019 (ECF No. 210) and the Third Count of Mylan’s Answer, Defenses and Counterclaims to First Amended and Supplemental Complaint (ECF No. 220) filed on February 28, 2019.

3. Amgen and Mylan stipulate that Mylan’s Fourth Count of Mylan’s Answer, Defenses and Counterclaims to First Amended and Supplemental Complaint (ECF No. 220) filed on February 28, 2019 for a declaratory judgment of invalidity of the ’997 Patent will be dismissed without prejudice.

4. Amgen and Mylan stipulate that this Stipulation and ~~Proposed~~ Order for Entry of Judgment of Non-Infringement Regarding U.S. Patent No. 9,643,997 resolves all pending disputes between the parties before the Court in this action.

Date: September 13, 2019

Respectfully submitted,

s/ Kent E. Baldauf, Jr.

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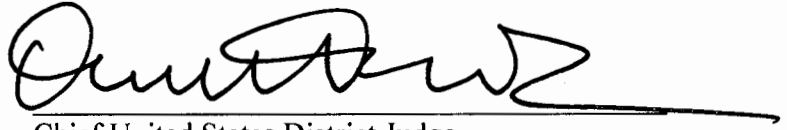
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 Pharmaceuticals Inc., Mylan N.V. and  
 Mylan Inc. and Defendant/Counterclaim  
 Plaintiff Mylan GmbH*

SO ORDERED AND ADJUGED this 16<sup>th</sup> day of September, 2019.

*the Clerk will close the case.*



Chief United States District Judge